V. DEVELOPMENT OF STANDARD

Various criteria have been used for categorizing the dustiness of the environment. Recent developments have made it clear that a method utilizing the capture and direct estimation of fibers of asbestos should be utilized for environmental measurement of exposure to asbestos. In the past, in the United States, asbestos fibers were measured by the impinger method which included counting particles as well as asbestos fibers.

The question still exists as to whether or not different varieties of asbestos fibers may have varying biological effects. This will not be answered until more definitive information is available on the specific etiological agent(s) and mechanisms of injury involved. The consumption of asbestos in this country is overwhelmingly in the form of chrysotile. Where other forms of asbestos are used, such as crocidolite and amosite, they are often mixed with chrysotile and are encountered alone, mainly in research and specialty situations. It would be extremely difficult on the basis of current information on biological effects and industrial practices to establish and administer separate standards for different types of asbestos.

The question also arises on the validity of basing standards on the number of respirable fibers in the air greater than 5 micrometers in length. It is fully realized that the fiber-size spectrum of respirable asbestos fibers in any particular industrial environment will range from that of bundles of fibrils in the upper respirable size to those of the individual fibrils in the sub-micron size. The type and grade of fibers, nature of processing, and controls in existence will greatly

influence the fiber-size spectrum (fiber length and diameter) in any given environment. The problem is further complicated by the lack of definitive information on the biologic response to fibers of different sizes. It is known, however, that the longer fibers show a dose-response relation to asbestosis, and may have a different behavior and degree of response than the shorter size fibers which may, in the lower and sub-micron range, tend to resemble more the physical behavior of non-fibrous respirable particulates. Since it would not be feasible to have a standard on the total respirable fibers which would necessitate the routine use of expensive and time-consuming techniques including electron microscopy, an index of exposure must be selected which, as nearly as possible, relates to the predominant biologic activity and dose-response of the size spectrum of fibers most commonly encountered. It is assumed for the present that the factor of safety associated with the standard will allow for differences in the size spectrum of respirable fibers that may be encountered.

The British, in evaluating respirable chrysotile fiber exposures in relation to the ongoing epidemiologic studies in the textile industry and for the basis of a standard for chrysotile, established as an index of exposure, fibers greater than 5 micrometers in length.[62] A substantial amount of information on the biologic effects of asbestos has, and is, being obtained using this parameter of exposure measurement. A review of the research in Britain, with concurrence on the rationale involved, made it prudent that we use the same definition of index-of-exposure on which to base criteria for standards. These criteria should be re-evaluated when, (1) more definitive information on the biologic response of asbestos including the agent(s) and dose-response data on different lengths of fiber is

available, (2) the spectrum of fiber lengths encountered in industry by types of asbestos and operations is ascertained, and (3) more precise epidemiologic data are developed.

To prevent fibrosis and excessive rates of neoplasia, such as mesothelioma, respiratory cancer, and gastrointestinal cancer, a standard for asbestos dust should be based on a concept of dose-response that includes not only the factor of fiber count times years of exposure but also that for total asbestos dust fibers retained over a number of years.

Thus, the effect after several decades of a one-time acute dose of limited duration which overwhelms the clearing mechanism, and is retained in the lungs, may be as harmful as the cumulative effect of lower daily doses of exposure over many years of work.

Basis for Previous Standards

The first standard for controlling exposure to asbestos dust was recommended by Dreessen et al.[63] in 1938 following a study of 541 employees in four asbestos textile plants where massive exposures occurred. A tentative limit for asbestos dust in the textile industry of 5 million particles per cubic foot (mppcf), determined by the impinger technique, was recommended. They found numerous well-marked cases of pneumoconiosis where concentrations exceeded 5 mppcf, but only three doubtful cases where concentrations were under 5 mppcf. However, only five persons had been exposed for more than 10 years to concentrations from 0.0 to 4.9 mppcf. None of the 39 persons exposed to concentrations below 2.5 mppcf showed evidence of asbestosis; but only six of these had been employed more than five years.

The study by Dreessen et al. had unavoidable limitations such as the fact that 333 of the 541 employees studied had worked less than five years in these textile mills, only 66 were employed as long as 10 years, and only 2 for more than 20 years. Furthermore, the average age of these asbestos textile workers was 32.1 years and only one of the four plants studied had been in operation for more than 15 years. Thus, the first standard established was based upon limited data. The authors recognized the limitations and stated that . . . "5 mppcf may be regarded tentatively as the threshold value for asbestos-dust exposure until better data are available."

The American Conference of Governmental Industrial Hygientists' (ACGIH) Threshold Limit Value (TLV) for asbestos dust was 5 mppcf

from 1946 to 1970. This limit was based on the study by Dreessen et al.[63] and subsequent investigations by others. In 1968 and 1969, ACGIH published notices of intended changes to lower the TLV to 12 fibers/ml >5 μm in length or 2 mppcf and they published in 1970 and 1971 a still lower limit of 5 fibers/ml >5 μm in length as a notice of proposed intended change. The conversion of data from mppcf to fibers/ml in all asbestos operations can only be done with considerable risk to the validity of the results. Lynch et al.[64] pointed out in 1970 the need for such conversion data and that the data reported in 1965[61] of the 12 fiber/ml equivalent to 2 mppcf relationship was obtained in textile mills and should not be applied to other product areas. Estimates of risk of disease in other product areas should be based on fiber counts since this method yields a more direct estimate of airborne asbestos concentration.

In 1968, the Committee on Hygienic Standards of the British Occupational Hygiene Society (BOHS) after reviewing medical evidence, results of studies made by the asbestos industry in the United Kingdom, and epidemiological data from the United States, published Hygienic Standards for Chrysotile Asbestos Dust.[62] It stated:

"1. As long as there is any airborne chrysotile dust in the work environment there may be some small risk to health. Nevertheless, it should be realized that exposure up to certain limits can be tolerated for a lifetime without incurring undue risks.

"2. The committee believes that a proper and reasonable objective would be to reduce the risk of contracting asbestosis to 1 percent of those who have a lifetime's exposure to the dust. By 'asbestosis'

this committee means the earliest demonstrable effects on the lungs due to asbestos.

"It is probable that the risk of being affected to the extent of having such early clinical signs will be less than 1 percent for an accumulated exposure of 100 fiber years per cm^3 or 2 fibers/cm^3 for 50 years, 4 fibers per cm^3 for 25 years or 10 fibers per cm^3 for 10 years.

"3. It is recommended that exposures which lie in certain ranges of dustiness be designated by categories according to the following scheme:

DUST CATEGORY	CONCENTRATION AVERAGED OVER 3 MONTHS (FIBERS/cm^3)
Negligible	0-0.4
Low	0.5-1.9
Medium	2.0-10.0
High	Over 10.0

"4. The levels are expressed in terms of the number of fibers per cm^3 greater than 5 μm in length as determined with the standard membrane filter method. Any other method can be used provided it is accompanied by appropriate evidence relating its results to those which would have been obtained with the standard membrane filter method.

"5. When it is necessary to work intermittently in a 'high dust' area an approved mask should be worn, provided that the concentration is no more than 50 fibers per cm^3 a higher standard of respiratory protection should be provided such as a pressure-fed breathing apparatus.

"Additional Recommendations

"1. It is recommended that where practicable an up-to-date employment record card be kept of every person which indicates, every calendar quarter, the category or categories in which he or she has been employed and in which he or she is recommended to work.

"2. All employees exposed to risk should be medically examined before employment. Periodic examinations should be made thereafter, annually.

"Notes:

"These hygienic standards are subject to review in the light of new evidence and improved methods of measurement.

"The standards are, in our opinion, the best that can be drawn from the existing data. These data are scanty and based on factory experience of continuous exposure during working hours. Due caution should be exercised in applying these standards to other patterns of exposure. As far as possible the dust exposures have been estimated conservatively and, in particular, in the period 1933-1950 the average hours of work were substantially greater than 40 per week.

"It is hoped to supplement the existing data in due course, when the standards will, if necessary, be modified. These standards will be formally reviewed in three years."*

In an unpublished paper, Williams, Baier, and Thomas compiled data from the Pennsylvania Department of Health files on exposure levels at

*As of 1/6/72 their standards as effective in May 1970 had not been revised. Per telephone conversation with Dr. S. Holmes, Secretary to the Asbestosis Research Council.

various textile processing operations in two plants. Their data included dust concentrations from 1930 through 1967 in one plant and from 1948 through 1968 in the second plant. Even though controlled exposures were, for the most part, below 5 mppcf and in many cases below the 1968 ACGIH Notice of Intended Change to 2 mppcf, 64 cases of asbestosis were reported from these two asbestos textile plants. The authors conclude that: "If asbestosis is to be prevented, airborne asbestos dust must be stringently controlled in the working environment. From these data a TLV of 3 mppcf would provide inadequate protection and the proposed 2 mppcf may not be substantiated."

Gee and Bouhuys,[65] in December, 1971, pointed out that on the basis of "reasonable probability," decisions must be made to control exposure to asbestos rather than from a precise definition of dose-response relationship, and "the present threshold limit value for asbestos should be lowered far below some recent proposal."

U. S. Emergency Standard

The present emergency standard for exposure to asbestos dust (29 CFR 1910.93a) published in the Federal Register, Vol. 36, No. 234, page 23207, December 7, 1971) is as follows:

> "The 8-hour time-weighted average airborne concentration of asbestos dust to which employees are exposed shall not exceed 5 fibers per milliliter greater than 5 microns in length, as determined by the membrane filter method at 400-450X magnification (4 millimeter objective) phase contrast illumination. Concentrations above 5 fibers per milliliter but, not to exceed 10 fibers per milliliter, may be permitted up to a total of 15 minutes in an hour for up to 5 hours in an 8-hour day."

The 1971 ACGIH tentative threshold limit value is 5 fibers/ml $> 5\ \mu m$ in length. Both are higher than the British standard of 2 fibers/cc by at least a factor of 1.5 times.

Basis for Recommended Standard

The number of studies that have collected both environmental and medical data and with a significant number of exposed workers is not sufficient to establish a meaningful standard based upon firm scientific data. The requirement to protect the worker exposed to asbestos is defined in a number of studies outlined in this document. The general recognition of the increasing number of cases of asbestosis, bronchogenic cancer, and mesothelioma indicates the urgent need to develop a standard at the present time.

NIOSH recognizes that these data are fragmentary and, as a result, a safety factor must be included in any standard considered. On this basis the research that did include both environmental and medical data, or where a standard or limit had been proposed, was given a careful and detailed study to determine its particular contribution to the development of a national standard.

The development of a standard for asbestos dust[66] in Great Britain and the evaluation made by the British Occupational Hygiene Society (BOHS) Sub-committee on Hygiene Standards for Asbestos,[62,66] which considered data to reduce the risk of asbestosis, was given great weight in the development of this asbestos standard. The BOHS fitted the data available to a dose-response curve and the conclusion was drawn that an accumulated exposure of 100 fiber-years/cm^3 would reduce early clinical signs to less than 1%. This would be 2 fibers/cm^3 for 50 years of exposure or 4 fibers/cm^3 for 25 years. According to Roach,[67] "The British Occupational Hygiene Society Standards Sub-committee on Asbestos expressed the view that a proper and reasonable objective would be to reduce exposures to below this level and thereby reduce the risk of

contracting asbestosis to less than 1% of those who have a lifetime exposure to the dust. For such workers, who may possibly work for 50 years, the long-term average concentration to which they are exposed would need to be less than 2 fibers/cm^3. For others, who will be exposed to asbestos dust in air for shorter periods, the long-term average concentration need not be so low, as long as their exposure will amount to less than 100 fiber-years/cm^3."

It is recognized that the British standard is based upon data not as precise as desired, but it does offer a mechanism for comparison with the ACGIH TLV and after three years of use no change has been recommended. The British standard was primarily based upon a study of 290 men employed for 10 years or longer between 1933-1966 in an asbestos textile mill. The environmental dust concentrations to which different workers had been exposed were estimated to have varied from 1 to 27 fibers/cm^3. The risk-exposure relationships were developed based upon basal rales and X-ray changes. In this study, basal rales were considered the key symptom since all workers exhibiting X-ray changes also exhibited basal rales.

In reviewing the values on the basis of the 100 fiber-years/cm^3 proposed by the British Hygiene Standards Committee, the following comparisons can be made between the British Standard and the Emergency U. S. Standard. Each standard is normalized to 100 fiber-years to account for differences in the working lifetime of the average asbestos worker. The Emergency U. S. Standard is based upon the ACGIH TLV which, in turn, is based upon an exposure time of 30 years to 5 fibers/ml> 5 um in length[68],

and the British, 50 years of exposure at 2 fibers/cm^3 > 5 um in length.

In summary:

	British	U. S. Emergency ACGIH
	2 fibers/cc	5 fibers/ml
Fiber-yrs/cc	100	150

The validity of this type of comparison has already been questioned in this document, i.e., the "K" factor used to change ACGIH impinger data to fiber counts.[61,64]

However, on this basis, data suggest that the ACGIH value is higher than the British value.

In addition to consideration of the British data, the comparison of British and ACGIH data suggests that the 30-year exposure value for a U. S. Standard should be about 3 fibers/cc 5 μm in length in order to assure that less than 1% of the workers exposed are at risk of developing the earliest clinical signs of asbestosis.

However, additional consideration must be given to the concepts of carcinogenesis as they relate to the determination of a standard for asbestos exposure. Any carcinogen (initiator) must be assumed, until otherwise proven, to have discrete, dose-dependent, irreversible and additive effects to cells that are transmissible to the cell progeny. Thus, initiation of malignancy following single small exposures to asbestos is possible, but of a low probability. With frequent or chronic exposure and a low dose-rate, the probability of initiation of malignancy is increased. Yet, even under optimal conditions of cell proliferation (in the presence of promotors) these malignant

transformations do not lead to instantaneous cancer, but remain insidious for a number of years (latent).

In protracted exposure, some of the total accumulated exposure is "wasted" (or irrelevant) as far as the initiator of cancer is concerned. Exposures in excess of the minimal initiation dose conceivably may shorten the latent period to some extent by substituting for other contributing factors that would have eventually been effectual in converting the latent tumor into a frank malignancy. Analytic methods used in the epidemiology of asbestos-induced cancers are unable to discriminate between the initiating dose and subsequent (wasted) exposure.

Consideration must also be given to the concept that an inverse relationship exists between dose-rate and the latent period. As the dose-rate becomes progressively lower, the latent period may approach or exceed the life span of exposed individuals.

Adherence to these concepts would argue toward reducing asbestos exposure substantially below those levels currently demonstrated to be associated with the disease. Such a course of action is consistent with the Surgeon General's ad hoc Committee on Evaluation of Low Levels of Environmental Chemical Carcinogens statement that, "for carcinogenic agents, a safe level for man cannot be established by application of our present knowledge."

Work practices in industries should be encouraged to develop work practice standards by the consensus method so that the lowest feasible environmental levels can be obtained. The following work practice standards are included in the emergency standard for asbestos and are included in the recommended standard:

(a) Asbestos cement, mortar, coatings, grout, and plaster shall be mixed in closed bags or other containers.

(b) Asbestos waste and scrap shall be collected and disposed of in sealed bags or other containers.

(c) All cleanup of asbestos dust shall be performed by vacuum cleaners or by wet cleaning methods. No dry sweeping shall be performed.

The need in industry for a proper precautionary label for asbestos and for other hazardous materials associated with the mining, production, and use of chemical compounds has existed for a number of years. The development of a labeling system for use as an occupational hazard warning system overlaps into so many other labeling areas, e.g., transportation of chemicals, fire fighting, use by the military, etc., that it would be necessary either to develop a separate system for use in relation to occupational exposures only, or to combine all the present systems into one.

The addition of one more labeling system compounds the multi-labeling requirement presently imposed on industry and creates one more labeling system the worker must recognize. Combining all systems into one requires the coordination of many governmental, professional, trade, manufacturing, and international and local organizations. Time required to accomplish this task is prohibitive in relation to the requirement for the immediate development of an occupational health standard for asbestos. As a result, NIOSH recommends as an interim system the adoption, with modification, of the system for the Identification of the Fire Hazards of Materials of the National Fire Protection Association and the Guide to Precautionary Labeling of

Hazardous Chemicals of the Manufacturing Chemists Association.

It is recognized that this system may not be the most appropriate system and may require additional development to permit the worker, himself, to use it to identify the hazards to which he is exposed and to learn the necessary precautions to assure him safe working conditions. (See Appendix II for the details and modification of the labeling system).

Summary of the Basis for the Recommended Standard

The recommendation for an environmental standard for asbestos is based upon health considerations and limited engineering feasibility data. The overriding considerations are the health effects.

Evidence indicates that past and current standards for fiber concentrations in the working places where asbestos fibers occur, though undoubtedly contributing to reduction of the severity and frequency of asbestosis, have not provided complete protection from exposure to asbestos, necessitating development of a new standard.

Consideration was given to previous reports and studies, recent data, and the present "state-of-the-art." It is recognized that additional data would be desirable to support an asbestos standard, but because of immediate need for worker protection, it is necessary to make a recommendation based on available studies and data. The following constraints in applicability of research data were considered in the development of the recommendations:

(a) Few epidemiological studies or clinical reports with supporting environmental data are available in the exposure range that must be considered.

(b) Environmental data on practically all studies were collected only over the last few years and/or they were collected by other techniques and expressed in terms other than fibers/cc.

(c) The environmental samples were expressly collected in many cases for control purposes rather than for research and, as a result, meaningful evaluations cannot be made.

(d) There is a lack of data to define with any degree of precision the threshold of development of neoplasms resulting from exposure to asbestos and the relationship of the latent period between exposure and development of neoplasms.

The standard recommended in this document is similar to the standard adopted by Her Majesty's Factory Inspectorate in 1969[66] (still in effect as of December 29, 1971), and more stringent than the recent U. S. Emergency Standard. It is felt to be feasible technologically for the control of the exposure to the worker and effective biologically for protection of the worker against asbestos-induced diseases.

Considerations of carcinogenesis indicated the need for a measure of prudence. As a result of this rationale, a factor was added to reduce the time-weighted average exposure to 2.0 fibers/cc> 5 um. A ceiling value of 10.0 fibers/cc> 5 um that was not to be exceeded was included to reduce the possibility of the short-term heavy exposures to asbestos that have been reported to cause mesothelioma. In addition, this should reduce the likelihood of diseases (malignant and non-malignant) resulting from exposures in excess of 30 years or with very long latent periods.

VI. COMPATIBILITY WITH EMISSION STANDARDS

The proposed national emission standard for asbestos was published in the Federal Register, Vol. 36, No. 235, pages 2342-2343 (40 CFR 61.20-61.24) by the Environmental Protection Agency. The emission standard will be applicable to asbestos mines, mills; building structures, or facilities within which manufacturing or fabricating operations involving the use of commercial asbestos; buildings or structures which have been or will be constructed or modified using asbestos insulation products; roadway facilities which would be surfaced or resurfaced using asbestos tailings.

The standards are based upon information derived from many sources, including health effect levels, meteorology, technical analysis of control capability, and consideration of economic impact. The overriding considerations are health effects. These standards are based upon specific operations and physical conditions and are limited in general to emissions to the atmosphere.

1. Emissions shall not exceed those which would be emitted from operations if proper engineering control had been installed (i.e. fabric filter, cyclone gas cleaning devices).

2. Visible emissions of particulate

3. Spraying of asbestos

4. Use of asbestos for surfacing or resurfacing of roads.

The use of procedural standards and visible emissions as the basis for evaluation for compliance with the standard are designed to minimize emission to the atmosphere. EPA determined that there

is no suitable technique for sampling and analysis of asbestos in ambient air or emission gases. This determination was made as only limited information had been developed from measuring fibers in community air. The use of high volume samplers for collection of samples and counting by light microscopic techniques similar to industrial hygiene methods has shown only small numbers of fibers in urban areas.[69]

It was felt that these values were low when compared to occupational health experience and values to few too use with confidence.[69]

As a result there is no direct comparison possible between the proposed national emission standards for asbestos and the recommended criteria for occupational exposure except to say that the levels of exposure to the general public on a 24-hour day, 7 days a week, basis would be lower, as would be expected, than occupational standards based on an 8-hour day, 40-hour work week.

The Illinois Pollution Control Board on November 30, 1971,[70] published a notice of proposed final draft of emission standards for asbestos that can be more easily related to the recommended occupational standard than those proposed by EPA. Illinois includes a provision that, "After June 30, 1972, a factory, plant or enterprise which engages in the processing or manufacturing of any asbestos-containing product shall discharge no visible emission of particulate matter from such manufacturing or processing into the ambient air and shall emit no concentrations of asbestos fiber in excess of 2 fibers per cubic centimeter of air."

The method of counting the asbestos fibers is that proposed by Edwards et al.[71] and similar to the technique proposed in Appendix I of this report. This proposed Illinois standard places a ceiling value of 2 fibers/cc on emissions from processing on manufacturing of asbestos containing products. In the explanation of the revision of the proposed Illinois regulation they state:

> "IV. Part V, controlling manufacturing sources, is changed to require an emission standard of 2 fibers per cubic centimeter and no visible emissions. While some testimony indicated the difficulty in measuring compliance with a numerical emission standard, overall the evidence establishes both the need (protection against the great proportion of invisible fiber) and the ease of measurement of such a criterion. A "no visible emission" standard has been added to the numerical standard to simplify enforcement against exceptionally dirty emission sources. A grace period, until June 30, 1972, has been added to permit acquisition of the necessary control equipment to attain the emission standard."

This air quality standard is, as it should be, more restrictive that an occupational standard due to differences in exposure time.

This proposed occupational standard would seem to be compatible with the proposed emission standard and each should complement the other in the control of asbestos exposure.

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